AUG 2 4 2000

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

1. Submitter's Name:	Guidant Corporation Advanced Cardiovascular Systems, Inc.
2. Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95054
3. Telephone:	408-845-3995
4. Fax:	408-845-3743
5. Contact Person:	Margaret Anderson
6. Date Prepared:	July 20, 2000
7. Device Trade Name:	HI-TORQUE WHISPER™ LS and MS Guide Wires with HYDROCOAT™ Hydrophilic Coating
8. Device Common Name:	Guide Wire
9. Device Classification Name:	Catheter Guide Wire (74DQX)
10. Predicate Device:	▪ ChoICE™ PT Guide Wire with ICE™ Hydrophilic Coating (K970244) ▪ ACS HI-TORQUE EXTRA S'PORT™ Guide Wire (K974773)

11. Device Description:

The HI-TORQUE WHISPER™ LS and MS Guide Wires with HYDROCOAT™ Hydrophilic Coating are guide wires with a 0.014″ diameter and available in 175 cm and 190 cm extendable lengths and a 300 cm exchange length. The proximal end of the 175 cm and 190 cm models are tapered to fit into the hypotube portion of the ACS DOC® Guide Wire Extension. This enables the physician to extend the working length of this guide wire to facilitate catheter exchanges. The wires are constructed with a stainless steel core wire. The proximal section of the core wire has a constant diameter and the distal core segment tapers in diameter to the tip. Attached to the distal core is a tip coil that provides radiopacity. The distal 30 cm of the core wire is jacketed with a polyurethane coating that is coated with a hyrophilic coating. The proximal section of the wire is coated with polytetrafluoroethylene. The distal tips of the guide wires are available either as a straight tip that is shapeable, or as a pre-shaped "J".

12. Intended Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of compatible stent devices during therapeutic intravascular procedures.

13. Technological Characteristics:

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate devices.

14. Performance Data:

In vitro bench testing and *in vivo* performance evaluations demonstrated that the HI-TORQUE WHISPER™ Guide Wires met the acceptance criteria and performed similarly to the predicate device. The following functional tests were performed: Tensile Strength, Torque Strength, Torqueability, Tip Flexibility, Coating Adhesion and Integrity Test and Lubricity Testing. No new safety or effectiveness issues were raised during the testing program. Therefore, the HI-TORQUE WHISPER™ LS and MS Guide Wires may be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2000

Ms. Margaret Anderson
Guidant Corporation
P.O. Box 58167
Santa Clara, CA 95052-8167

Re: K002206
HI-TORQUE WHISPER™ LS and MS Guide Wires with HYDROCOAT™ Hydrophilic Coating
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: July 20, 2000
Received: July 21, 2000

Dear Ms. Anderson:

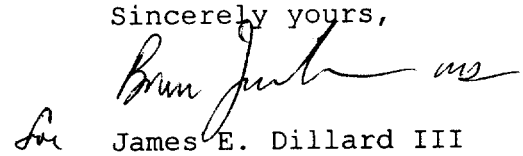
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Names:

- HI-TORQUE WHISPER™ LS (Light Support) Guide Wire with HYDROCOAT™ Hydrophilic Coating
- HI-TORQUE WHISPER™ MS (Middle Support) Guide Wire with HYDROCOAT™ Hydrophilic Coating

Indications for Use: To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA), percutaneous transluminal angioplasty (PTA) and compatible stent devices during therapeutic intravascular procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Division of Cardiovascular & Respiratory Devices
510(k) Number K002206

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Prescription Use_____ OR Over-The-Counter_____
(Per 21 CFR 801.109) (Optional Format 1-1-96)